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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/596,073	06/16/2000	William J. Bologna	254/304	2949

28765 7590 08/22/2003

WINSTON & STRAWN  
PATENT DEPARTMENT  
1400 L STREET, N.W.  
WASHINGTON, DC 20005-3502

EXAMINER
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PRYOR, ALTON NATHANIEL

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 08/22/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/596,073

Applicant(s)

BOLOGNA ET AL.

Examiner

Alton N. Pryor

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7, 10, 15, 16, 19, 20 and 23-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 10, 15, 16, 19, 20 and 23-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

I. Rejection of claims 1-5,7,10,15,16,19,20 and 23-34 under 35 USC 103 (a) will be maintained for reasons on record and reasons as follows.

Applicant argues that a particular combination of polymers provide extended release and that the polymers are combined in a manner that provides progressive hydration. Applicant argues that Timpe would not be understood to suggest use of the particular polymer combination or their combination to provide progressive hydration. Applicant argues that Timpe's focus and goal --- is release and bioavailability which are completely inconsistent with progressive hydration. Examiner argues that Applicant does not specify a particular polymer combination, but rather just merely recites a composition comprising 1) a bioadhesive, water-insoluble, water-swelling cross-linked polycarboxylic polymer and 2) a water-soluble polymer. The claim mentions no particular polymer combination (amounts / ratios). Timpe reads on the invention since Timpe also suggests a combination of the same polymers. See column 3 lines 3-9,37-43. In the absence of unexpected results, one having ordinary skill in the art would have expected the prior art composition to have extended release properties and the ability to progressively hydrate.

#### ***Claim Objection to New Matter is the Specification***

The amendment filed 11/28/02 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material

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which is not supported by the original disclosure is as follows: 1) the time it takes for a tablet to hydrate is decreased; 2) low levels of lactose and corn starch are probably best suited to buccal administration where 12 hours of delivery is usually sufficient; 3) better suited for vaginal administration where release is often required over a period of days; 4) inventors have discovered that by progressively increasing the amount of lactose and corn starch and progressively decreasing the amount of carbomer 974P.

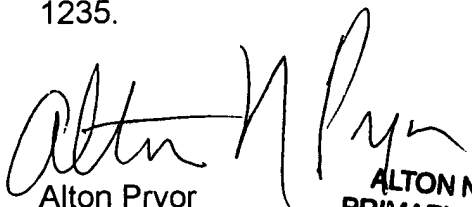
Applicant is required to cancel the new matter in the reply to this Office Action.

***Telephonic Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 703 308-4691. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703 308-4628. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

  
Alton Pryor  
Patent Examiner  
AU 1616

ALTON N. PRYOR  
PRIMARY EXAMINER